

Claims:

Sub B1
A solid oral dosage form comprising

- a) an active agent containing an effective amount of valsartan or a pharmaceutically acceptable salt thereof and
- b) pharmaceutically acceptable additives suitable for the preparation of solid oral dosage forms by compression methods

wherein the active agent is present in an amount of more than 35 % by weight based on the total weight of the solid oral dosage form.

2. A solid oral dosage form according to claim 1 wherein the active agent is present in an amount of more than 50 % by weight.

Sub B2
3. A solid oral dosage form according to claim 1 ~~or claim 2~~ wherein the active agent is present in an amount ranging from 57 to 62 % by weight.

4. A solid oral dosage form according to ^{1 claim 1} ~~any of the preceding claims~~ wherein the active agent consists entirely of valsartan or a pharmaceutically acceptable salt thereof in a dosage of from between about 10 and 250 mg.

5. A solid oral dosage form according to ^{claim 1} ~~any of the preceding claims~~ wherein the dosage range is from 40 to 160 mg.

6. A solid oral dosage form according to ^{claim 1} ~~any of the preceding claims~~ wherein the dosage is 40 mg, 80 mg or 160 mg.

7. A solid oral dosage form according to ^{claim 1} ~~any of the claims 1 to 3~~ wherein the active agent consists of an effective amount of valsartan or a pharmaceutically acceptable salt thereof and an effective amount of hydrochlorothiazide (HCTZ).

8. A solid oral dosage form which comprises as therapeutic agents an effective amount of valsartan or a pharmaceutically acceptable salt thereof; an effective amount of HCTZ; and, pharmaceutically acceptable additives suitable for the preparation of solid oral dosage forms by compression methods.

9. A solid oral dosage form according to ^{claim 8} ~~claims 7 or 8~~ comprising a unit dose of about 10 to 250 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of about 6 to 60 mg of HCTZ.

10. A solid oral dosage form according to ^{claim 8} ~~any of the claims 7 to 9~~ comprising a unit dose of about 50 to 100 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of about 10 to 30 mg of HCTZ.

11. A solid oral dosage form according to ^{claim 8} ~~any of the claims 7 to 9~~ comprising a unit dose of about 80 to 160 mg of valsartan or a pharmaceutically acceptable salt thereof and a unit dose of 12.5 mg or 25 mg of HCTZ.

12. A solid oral dosage form according to ^{claim 8} ~~any of the preceding claims~~ which comprises microcrystalline cellulose as a pharmaceutically acceptable additive.

13. A solid oral dosage form according to ^{claim 8} ~~any of the preceding claims~~ which comprises crosslinked polyvinylpyrrolidone (PVP) as a pharmaceutically acceptable additive.

14. A solid oral dosage form according to claim 12 wherein the microcrystalline cellulose is present in an amount of from 15 to 25 % by weight.

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15. A solid oral dosage form according to claim 13 wherein the crosslinked PVP is present in an amount of from 10 to 30 % by weight.

16. A solid oral dosage form according to ^{claim 8} ~~any of the preceding claims~~ in the form of a tablet.

17. A solid oral dosage form according to ^{claim 8} ~~any of the preceding claims~~ in the form of a dragée.

18. A process of forming a solid oral dosage form as defined in ^{claim 8} ~~any of the preceding claims~~ comprising the steps of

- i) grinding the active agent and pharmaceutically acceptable additives,
- ii) subjecting a mixture of the ground active agent and additives to compression to form a copri~~mate~~
- iii) converting the copri~~mate~~ into granulate and
- iv) compressing the granulate to form the solid oral dosage form.

19. A process according to claim 18 wherein the compression step ii) is carried out using roller compaction or slugging techniques.

20. A process according to claim 18 ~~or 19~~ wherein step iii) is carried out by screening or milling the copri~~mate~~.

21. A process according to ^{claim 18} ~~any of the claims 18 to 20~~ wherein the granulate is compressed without first being sized.

- A *Sub B5*
22. A process according to ~~any of the claims 18 to 21~~ *claim 18* wherein the granulate is formed under a pressure of from 25 to 65 kN.
23. Coprimates obtained by roller compaction or slugging according to claim 19.
24. Granulate obtained according to the process according to claim 18.
- A *Sub B6*
25. A solid oral dosage form produced according to a method as defined in ~~any of the claims 18 to 22~~ *claim 18*.
26. A solid oral dosage form substantially as hereinabove defined with reference to any of the Examples.
27. Use of a solid oral dosage form as defined in any of the claims 1 to 17 in a method of treating hypertension (whether of the malignant, essential, reno-vascular, diabetic, isolated systolic, or other secondary type), congestive heart failure, angina (whether stable or unstable), myocardial infarction, arteriosclerosis, diabetic nephropathy, diabetic cardiac myopathy, renal insufficiency, peripheral vascular disease, left ventricular hypertrophy, cognitive dysfunction, e.g. Alzheimer's, stroke, headache and chronic heart failure.
- add A1*
- add B7*